

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	MAIL STOP AF
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Takatomo Hisamatsu et al.)	Group Art Unit: 3773
)	
Application No.: 10/603,664)	Examiner: MELISSA K. RYCKMAN
)	
Filing Date: June 26, 2003)	Confirmation No.: 3993
)	
Title: CATHETER AND MEDICAL TUBE)	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Claims 1-3, 6, 11 and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,036,067 (hereinafter Wijeratne) in view of U.S. Patent No. 5,911,715 (hereinafter Berg). Claims 4, 8-10 and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over, Wijeratne in view Berg and U.S. Patent No. 5,217,482 (hereinafter Keith). Applicants respectfully request review of these rejections.

A. Claimed Subject Matter

Claims 1, 25 and 29 are the only independent claims in this application. Each of Claims 1, 25 and 29 defines a catheter. The catheter defined in independent Claim 1 includes, *inter alia*, a proximal shaft (exemplified as element 15 in the specification), an intermediate member (exemplified as element 14 in the specification) connected to a front side of the proximal shaft, a distal shaft (exemplified as element 13 in the specification) connected to a front portion of the intermediate member, and a balloon (exemplified as element 12 in the specification) connected at a front portion of the distal shaft. The recited proximal shaft includes a main shaft portion (exemplified as element 153 in the specification) and a proximal shaft insertion portion (exemplified as element 152 in the specification) formed by spiral slit on a front portion of the proximal shaft and inserted into a rear portion of the intermediate member, a pitch of the spiral slit becoming gradually shorter toward a distal

end of the spiral slit, as exemplified in Fig. 5 of the specification. The catheters defined in Claims 25 and 29 include similar features.

B. The Examiner's Position

The Official Action relies on Wijeratne based on the belief that Wijeratne discloses a catheter having a proximal shaft (transition tube 32), an intermediate member (hub 38)¹ connected to a front side of the proximal shaft (transition tube 32), a distal shaft (outer body tube 22) connected to a front portion of the intermediate member (hub 38), and a balloon (balloon member 21) connected at a front portion of the distal shaft (outer body tube 22), with the proximal shaft (transition tube 32) including a main shaft portion (transition tube 32) and a proximal shaft insertion portion (coil member 31) formed by spiral slit on a front portion of the proximal shaft (transition tube 32) and inserted into a rear portion of the intermediate member (hub 38). The Official Action also takes the position that it would have been obvious to modify Wijeratne's coil member 31 to have a pitch that becomes gradually shorter toward its distal end.

As discussed below, the rejection is improper and without basis as it is premised upon an improper representation of what Wijeratne actually discloses, and fails to establish a prima facie case of obviousness.

C. Wijeratne does not disclose a proximal shaft insertion formed by spiral slit on a front portion of a proximal shaft and inserted into a rear portion of an intermediate member

As discussed in lines 36-41 of column 5 of Wijeratne, the coil member 31 is wound on a mandrel by a coil winder such that its outer diameter is somewhat less than the inner diameter of the tubing for preparing the transition tube 32. The mandrel-supported wound coil is inserted into the inner diameter or lumen of the tubing, and the mandrel is removed.

¹ Earlier Official Actions designated the "distal end of 32" as an intermediate member. The present Official Action now designates the hub 38 as an intermediate member. The previous designation of the "distal end of 32" as an intermediate member was evidently mistakenly carried over in the middle of page 2 of the Official Action.

As discussed above, the Official Action takes the position that the transition tube 32 is a proximal shaft, that the coil member 31 is a proximal shaft insertion portion formed by spiral slit on a front portion of the proximal shaft/transition tube 32, and that the hub 38 is an intermediate member. However, it is clear from the above-noted portion of Wijeratne's disclosure that the coil member 31 is not a spiral slit formed on a front portion of the transition tube 32. Instead, the coil member 31 is a separate element inserted within the transition tube 32. Thus, Wijeratne does not disclose a proximal shaft insertion portion formed by spiral slit on a front portion of a proximal shaft.

Moreover, even if the coil member 31 could be considered a spiral slit formed on a front portion of the transition tube 32, it is quite clear from a careful study of Wijeratne's Fig. 2 that the coil member 31 is not inserted into a rear portion of the intermediate member/hub 38. Indeed, the rightmost end of the coil member 31 in Wijeratne's Fig. 2 is substantially spaced from the leftmost end of the hub 38. Thus, Wijeratne does not disclose a proximal shaft insertion portion formed by spiral slit inserted into a rear portion of an intermediate member.

D. The Official Action has failed to establish a prima facie case of obviousness with respect to the recited pitch of the spiral slit becoming gradually shorter toward a distal end of the spiral slit

As discussed in lines 4-17 of column 5 of Wijeratne, the coil member 31 is preferably wound so as to provide a very small gap or substantially no gaps between adjacent turns of the coil, to minimize the risk of coil turn overlap as the coil bends and to retain adequate torsional and column strength so that twisting, pushing and pulling forces imparted onto the transitional assembly 15 by the proximal cannula 13 will not cause kinking or permanent twisting of the transitional assembly.

The Official Action correctly notes that the coil member 31's pitch does not become gradually shorter toward its distal end. However, without identifying a single prior art coil member having a variable pitch, the Official Action goes on to state that "Wijeratne does teach that the pitch varies to what is necessary to achieve adequate torsional strength in the

desired application" and that "(it) would have been obvious...to have the pitch decrease towards the distal end, as it is commonly known that a more flexible distal end is necessary to pass through the vasculature smoothly". (Official Action, page 4). Applicants respectfully disagree.

Applicants respectfully submit that the above-noted portion of Wijeratne teaches away from modifying coil member 31 to have a pitch that become gradually shorter toward its distal end, i.e., gradually longer toward its proximal end. Specifically, the above-noted portion of Wijeratne emphasizes that the gaps between adjacent turns of the coil should be minimized to the extent possible to provide the highest possible torsional and column strength and to minimize the risk of coil turn overlap. Thus, an ordinarily skilled artisan would have, if anything, minimized the pitch throughout the entire coil member 31, and would not have modified the coil member 31 to have various portions of longer and shorter pitch.

Moreover, even assuming that an ordinarily skilled artisan would have looked to modify the coil member 31 to have a more flexible (i.e., a less stiff) distal end, the Official Action has failed to establish that a coil member would be more flexible (i.e., less stiff) at portions having a lower pitch. Indeed, Applicants respectfully submit that, if anything, the opposite relationship would hold.

For at least the reasons above, the Examiner has not established a *prima facie* case of obviousness in the rejection under 35 U.S.C. § 103(a). Therefore, the outstanding rejection under 35 U.S.C. § 103(a) is improper and should be withdrawn.

Respectfully submitted,

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